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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/315,298 05/20/99 TENG

C ISIS-3510

HM22/0920

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EXAMINER

EPPS, J

ART UNIT

PAPER NUMBER

1635

DATE MAILED:

18
09/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/315,298

Applicant(s)

TENG ET AL.

Examiner

Janet L. Epps

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-- Th MAILING DATE of this communication app ars on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10, 12, 13, 15, 17-20, 46, 48-64, 80 and 83 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10, 12, 13, 15, 17-20, 46, 48-64, 80 and 83 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 122.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: The second application (which is called a continuing application) must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the continuing application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *In re Ahlbrecht*, 168 USPQ 293 (CCPA 1971). In the instant case, Applicant's claim of priority to Application 09/108,673 as a continuation is improper, the claim to priority is more appropriately is a CIP instead of a continuation. The specification of 09/108,673 does not fully support the claimed subject matter of the instant application (MPEP § 201.07). The instant application contains subject matter that would constitute new matter if inserted in the original application of both 09/108,673 and its parent application 08/886,829. For example, the instant application discloses that the compositions of the present application are useful for "non-parental" administration, which refers to "contacting, directly or otherwise, to all or a portion of the alimentary canal, skin, eyes, pulmonary tract, urethra or vagina or an animal (specification page 3, lines 13-16). However, the specification of 09/108,673 discloses that the compositions are useful for "alimentary delivery", which refers to "oral, rectal,

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endoscopic, or sublingual/buccal administration (page 7, lines 14-17)." Additionally, the compositions of the present invention read on pharmaceutical compositions comprising an emulsion and an oligonucleotide (claim 1 of the instant application, and page 1, lines 16-18), in contrast the compositions of the earlier filed patent applications comprise a penetration enhancer and an oligonucleotide (page 1, lines 9-12).

Therefore, due to the inconsistency regarding the disclosure of the instant application and that of the earlier filed applications of 09/108,673 and 08/886,829 Applicants are not entitled to the earlier filing date of application 08/886,829, filed July 1, 1997.

Response to Arguments

3. Claims 1-7 and 10 remain rejected under 35 USC 102(b) as anticipated by Narayanan et al. for the reasons of record in the Official Action mailed 9-12-2000.

Applicant's arguments filed 7-2-01 have been fully considered but they are not persuasive. Applicants traverse this rejection on the grounds that the Narayanan patent does not disclosed penetration enhancers as defined in the specification as filed, particularly wherein the penetration enhancers include "but are not limited to members of molecular classes such as surfactants, fatty acids, bile salts, chelating agents, an non-chelating non-surfactant molecules." (specification, page 8, lines 10-12). Contrary to Applicant's assertions, the compositions of Narayanan et al. may comprise oligomers associated with targeted carriers, wherein said carriers are "non-chelating non-surfactant molecules" such as antibody or receptor fragments, ligand molecules, hormones, and enzymes or may be provided in liposomes or micelles for more efficient

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delivery into cells. Thus, Narayanan et al. disclose penetration enhancers that are useful in facilitating the transport of oligomers into cells (col. 5, lines 45-66).

4. Claims 1-7, 19-20, 46-64, 80 and 83 remain rejected under 35 U.S.C. 102(e) as being anticipated by Bennett et al. (US 6,111,094A1), for the reasons of record in the Official Action mailed 9-12-2000.

Applicant's arguments filed 7-2-01 have been fully considered but they are not persuasive. Applicants traverse this rejection on the grounds that in view of Applicant's claim of priority, which entitles the present application an effective filing date of July 1, 1997, the disclosure of the Bennet patent that serves as the basis for the rejection is not disclosed in its immediate parent (US patent 5,843,738). Therefore, Applicants argue that the subject matter over which the present inventions stand rejected has an effective filing date of April 17, 1998, the date on which the Bennett patent was filed.

However, contrary to Applicant's arguments Bennett et al. (US patent 5,843,738) clearly discloses pharmaceutical compositions comprising an antisense oligonucleotide, wherein said composition may be formulated in a pharmaceutical composition, which may include carriers, thickeners, diluents, buffers, preservatives, surface active agents, liposomes or lipid formulations and the like, in addition to the oligonucleotide.

Pharmaceutical compositions may also include one or more active ingredients such as antimicrobial agents, anti-inflammatory agents, anesthetics, and the like, in addition to oligonucleotide. Additionally, the compositions for oral administration of Bennett et al. also include powders or granules, suspensions or solutions in water or non-aqueous media, capsules, sachets, or tablets. Thickeners, flavorings, diluents, emulsifiers,

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dispersing aids or binders may be desirable. Formulations for parenteral administration may include sterile aqueous solutions that may also contain buffers, liposomes, diluents and other suitable additives (col. 9, lines 1-32). Moreover, the oligonucleotides according to SEQ ID NO: 1 and 55 are clearly disclosed as ISIS 2302 and ISIS 1939 of the Bennett et al. invention (col. 17, Table 1). The instant claims remain rejected as anticipated by Bennett et al.

5. Claim 46 remains rejected under 35 U.S.C. 102(e) as being anticipated by Wong et al. (US Patent No. 6,120,803); Claims 1-7, 10, 12-13, 15, 17-20, and 46-62 remain rejected under 35 U.S.C. 102(e) as being anticipated by McKay et al. (US Patent No. 5,877,309) for the reasons of record set forth in the Official Action mailed 9-12-2000.

Applicant's arguments filed 7-2-01 have been fully considered but they are not persuasive. Applicants traverse this rejection on the grounds that in view of Applicant's claim of priority, which entitles the present application an effective filing date of July 1, 1997, the Wong et al. and McKay et al. patents do not qualify as prior art under 35 USC § 102(e). However, as stated above, the present application is not entitled to an effective filing date of July 1, 1997, there the instant claims remain rejection under 35 USC § 102(e) over Wong et al. and McKay et al. for the reasons of record set forth in the Official Action mailed 9-12-2000.

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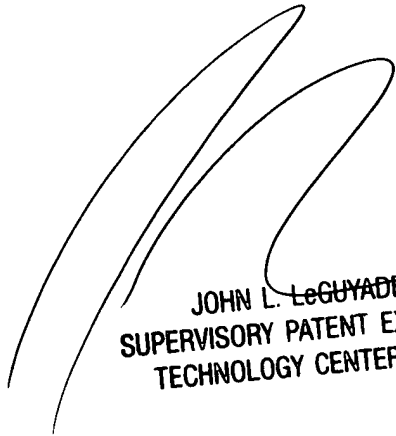
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps whose telephone number is 703-308-8883. The examiner can normally be reached on Mondays through Friday, 9:00AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps
Examiner
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JLE
September 14, 2001



JOHN L. LEGUYADER
SUPERVISORY PATENT EXAMINER
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